REMARKS

Introduction

Claims 15-17, 22-23, and 27-30 are pending. Claim 15 has been amended. Support for these amendments can be found throughout the specification, for example, in the original claims. No new matter has been added.

Claims 1-14, 18-21, and 24-26 are cancelled without prejudice to the subject matter disclosed therein. Applicant expressly reserves the right to pursue the subject matter of the cancelled claims in this application or in another application.

Rejection under 35 U.S.C. §112

The Examiner has rejected claims 16 and 17 under 35 U.S.C. § 112 as allegedly lacking antecedent basis for the phrase "substance." To expedite prosecution, claim 15 has been amended to provide antecedent basis for the term at issue. This rejection is believed to be overcome in view of the amended claims. Applicant respectfully requests that the rejection be withdrawn.

Rejection under 35 U.S.C. §102

The Examiner has rejected claims 15-17, 23, and 27-30 under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent Number 7,244,431 issued to Focke et al. (the '431 patent). Applicant traverses. For the sake of brevity, independent claim 15 is discussed below but all dependent claims are believed to be patentable as well by virtue of at least their dependency.

Amended claim 15 is directed to a pharmaceutical composition for sublingual, buccal or enteric administration comprising a substance comprising a peptide having a molecular weight of less than 10 kDa obtainable by hydrolysis with chymotrypsin or any other protease of an antigenic structure which induces graft rejection, allergic reaction or autoimmune disease, said antigenic structure being a protein, and said peptides being fragments of said protein.

A difference between the '431 patent and claim 15 is that the composition of the claimed invention comprises a mixture of peptides from the hydrolysis of allergens and not specific peptides. The '431 patent uses a pharmaceutical composition having peptides which comprise 8 to 50 amino acids. See, e.g., the Abstract. These peptides comprise at least 3 amino acids which appear in close vicinity on the surface of the protein and are solvent exposed. *Id.* From the whole length Bet v 1 allergen, 6 specific peptides are used. See table 1.

In contrast, the claimed invention requires hydrolyzed fragments of allergens, i.e. the product comprises the complete hydrolyzed antigenic structure with a MW < 10,000. This can, for example, be derived from the examples of Applicant's specification. In example 1, the complete 13-lactoglobulin (BLG) is hydrolyzed and the remaining product (after removal of chymotrypsin and unhydrolyzed protein) is used. The same is true for example 2 regarding hydrolysis of insulin.

Moreover, the Examiner has also rejected dependent claims 28 and 29 which cover formulations designed for buccal and enteric administration, but these features are not disclosed the '431 patent. The '431 patent discloses some ways of administration including subcutaneous, intramuscular, intravenous as well as sublingual, oral or nasal administration. It does not disclose formulations for buccal or enteric administration, which are distinct from oral administration.

One of skill in the art would interpret oral administration as meaning that the product is introduced into the body through the mouth. Typically such products are digested in the acidic stomach environment, where the contents of the oral formulation are released. As shown in the specification, e.g., on page 5, paragraph 3, buccal administration is a specific administration route wherein the absorption is via the oral cavity. Enteric administration is a specific administration route wherein the drug passes through the stomach and is delivered intact in the intestine where it is absorbed in the ileum, duodenum or jejunum (see page 5, paragraph 4). In fact, in some cases enteric administration is performed using a suppository formulation which does not involve oral administration. These are distinct formulary features for the compositions in the claims that are not disclosed in the '431 patent.

For at least these reasons, the rejection under 35 U.S.C. §102 is improper. Applicant requests that it be withdrawn.

Rejection under 35 U.S.C. §103

The Examiner has rejected claims 15-17, 22, 23, and 27-30 under 35 U.S.C. §103(a) as allegedly being obvious in view of the '431 patent and U.S. Patent Number 5,898,037 issued to Marx (the '037 patent). Applicant traverses.

The deficiencies of the '431 patent discussed above are not remedied by the '037 patent, which deals with formulations of magnesium compounds for local administration. The claims require a mixture of peptides from the hydrolysis of allergens and this feature is not shown or fairly suggested in the cited references, even if combined. Moreover, the routes of administration of claims 28 and 29 for the claimed formulation are not shown or fairly suggested in the cited references.

For at least these reasons, the rejection under 35 U.S.C. §103(a) is improper because it fails to show all elements of the claims. Applicant respectfully requests that this rejection be withdrawn.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of the claims and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

Dated: September 2, 2009

Respectfully submitted,

By: /Matthew E. Kelley/
Matthew E. Kelley
Registration No.: 55,887
VENABLE LLP
P.O. Box 34385
Washington, DC 20043-9998
(202) 344-4000
(202) 344-8300 (Fax)
Attorney/Agent For Applicant

#1054940v1